I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: 7/16/08
Electronic Signature for James F. Kamp: /James F. Kamp/

Docket No.: 65306-0092
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Timothy A. Becker et al.

Application No.: 10/738,317

Confirmation No.: 8901

Filed: December 17, 2003

Art Unit: 1618

For: COMPOSITIONS AND METHODS FOR IMPROVED OCCLUSION OF VASCULAR DEFECTS

Examiner: J. W. Rogers

Mail Stop Amendment
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR § 1.132

Dear Sir:

I, Timothy A. Becker, Ph.D., being of majority age, hereby state and declare as follows:

1. I am the first named inventor on U.S. Patent Application No. 10/738,317, entitled "COMPOSITIONS AND METHODS FOR IMPROVED OCCLUSION OF VASCULAR DEFECTS," filed 12/17/2003 ("the '317 application").

2. I hold a doctorate degree in Bioengineering from Arizona State University, with my doctoral dissertation titled "APPLICATION OF CALCIUM ALGINATE AS AN ENDOVASCULAR EMBOLIZATION MATERIAL FOR VASCULAR LESIONS." I am the author of my doctoral dissertation, which was approved in May 2001. After leaving Arizona State University, I joined the University of Michigan – Ann Arbor as a Post-Doctoral Senior Research Associate, where I performed work underlying the present application.

3. I have carefully reviewed the Non-Final Office Action mailed on January 17, 2008 (the "Office Action"), as well as the cited references Cochrum, U.S. Patent no. 5,614,204 and my doctoral dissertation from Arizona State University, as well as excerpts from Novamatrix online

EXHIBIT A

documents cited in the Office Action. I have reviewed and am familiar with a previous cited reference U.S. 2001/00331978 ("the Kipke application") and its related issued patent, U.S. Patent 6,592,566.

4. I have personal knowledge of the work underlying my doctoral dissertation and the present application. I am also a named inventor in the Kipke application and patent and have personal knowledge of the technology disclosed and discussed in that application, which is based in part on my doctoral work.

5. At pages 6-8 of the Office Action, the Examiner makes certain statements and assumptions concerning the alginates discussed in my doctoral dissertation and used in my underlying doctoral research. As some examples, the Examiner cites to my doctoral dissertation with respect to the use of purified high guluronic acid content ("PHG") purchased from Pronova. (Page 6). The Examiner also cites to certain Novamatrix online catalog materials for the proposition that "Pronova UP-LVG is known to have a molecular weight range of 75,000 to 200,000 g/mol, within applicants [sic] claimed range." (*Id.*) The Examiner also states that "[r]egarding claims 35 and 37 since the PHG alginates of Becker are the same as the alginates claimed by applicants it is obvious that the same polymer will have the same properties including viscosity." (Page 8). The Examiner also states that "[a]lso on page 30 of the dissertation a figure of viscosity vs. concentration shows that at 1 wt% PHG appears to have a viscosity less than 25cP." (*Id.*) The Examiner then concludes, along with other comments, that the invention as claimed is obvious.

6. With respect to the source and nature of the alginates, the work underlying my dissertation was the same as the work underlying the Kipke application, filed in February 2001 before the approval of my doctoral dissertation in May 2001 and on which I am a named co-inventor. In my previous October 2007 Declaration under 37 CFR §1.132 submitted in this matter, I explained why the Examiner's conclusion that the alginates used in my previous work were the same as the alginates disclosed in the present application was unsupported. My previous comments apply here as well.

7. The alginates discussed in my doctoral dissertation, the Kipke application, and the present application were purchased from the same source, Pronova. However, no characterization

of molecular weight was available from the vendor on the batches of alginate used at the time of my doctoral work and dissertation. The only known characterization was the G-acid content and the purity. Therefore, the optimization of alginates discussed in my doctoral dissertation originally focused on G acid content and purity only. All testing disclosed in my doctoral dissertation was done with the same batches of alginate. The purified, high G-acid (PHG) batch of alginate was identified as optimal in my doctoral dissertation.

8. Subsequently, when the original batch of PHG alginate was exhausted, a new batch of the PHG-class of alginate was ordered from Pronova. The new PHG batch of alginates was made to the specifications disclosed in my doctoral dissertation. However, the resulting injectable liquid viscosity and final gel strength were significantly different from the original properties disclosed in my doctoral dissertation. The vendor had sent the same class of alginate (PHG), however, the original batch of PHG alginate was no longer available. In addition, although Pronova had begun classifying the new batches of PHG alginates by their molecular weight, this information was not available for the original batch of PHG alginate. Thus, the MW of the alginate material in my doctoral dissertation is unknown.

9. The Examiner's statement, based on the Novamatrix online catalog materials, that "Pronova UP-LVG is known to have a molecular weight range of 75,000 to 200,000 g/mol, within applicants [sic] claimed range", has no bearing on the MW of the alginate disclosed in my doctoral dissertation because the information cited by the Examiner relates only to present knowledge about the molecular weight of certain types of Pronova UP-LVG sold currently by Novamatrix. Based on my review of the Novamatrix online documents, there is no proof of when that molecular weight information was first made publicly available through those documents. I am not aware of any information, nor has the Examiner shown any, that demonstrates the molecular weight of the PHG used in my doctoral work or shows that knowledge of that molecular weight was known at any time before the present application was filed.

10. Without a way to determine the molecular weight of the alginates used on my doctoral work, part of our original work underlying the present application was to characterize the entire range of PHG alginates then currently available from Pronova. In doing so, we discovered the properties of the molecular weight ranges disclosed and claimed in the present application.

11. With respect to the Examiner's comments concerning the figure on page 30 of my doctoral dissertation, based on my personal knowledge as the document's author, I disagree with the assertion that the figure "shows that at 1 wt% PHG appears to have a viscosity less than 25cP." The figure was not prepared to disclose such information, and the figure is the same figure as Figure 7a in the related Kipke et al. patent, U.S. Patent 6,592,566, where the Figure clearly shows the distinction from present claims 35 and 37. In addition, data on which the figure is based are set out in Table 2.2 at page 27 of my doctoral dissertation, which clearly shows the complete lack of any viscosity data related to 1% PHG.

12. I further declare that all statements made on my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 7/16/08

Signature: Timothy A. Becker, Ph.D.